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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/847,670	05/02/2001	Barry C. Finzel	6263.N	4815

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EXAMINER	
SMITH, CAROLYN L	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 09/16/2002 7

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application N .	Applicant(s)	
	09/847,670	FINZEL ET AL.	
	Examiner	Art Unit	
	Carolyn L Smith	1631	

-- The MAILING DATE of this c mmunication appears on the cover sheet with the correspondence address --

Peri d f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

4)☒ Claim(s) *1-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-48* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachm nt(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The art unit designated for this application has changed. Applicant(s) are hereby informed that future correspondence should be directed to Art Unit 1631.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5, drawn to a molecule or molecular complex, classified in class 435, subclass 235.1.

II. Claims 6-13, drawn to a scalable three-dimensional configuration of points and a machine-readable data storage medium, classified in classes 702 and 211, subclasses 27 and 41.12, respectively. If this Group is elected then the below summarized specie election is also required.

III. Claim 14, drawn to a method for obtaining structural information about a molecule or a molecular complex, classified in class 702, subclass 27. If this Group is elected then the below summarized specie election is also required.

IV. Claim 15, drawn to a method for homology modeling a Hepatitis C virus helicase homolog, classified in class 703, subclass 2. If this Group is elected then the below summarized specie election is also required.

V. Claims 16-24, drawn to a computer-assisted method for identifying an inhibitor of Hepatitis C virus helicase activity, classified in class 702, subclass 19. If this Group is elected then the below summarized specie election is also required.

VI. Claims 25-27, drawn to a method of making an inhibitor of Hepatitis C virus helicase activity, classified in class 435, subclass 7.71.

VII. Claims 28-30, drawn to an inhibitor of Hepatitis C virus helicase activity and a pharmaceutical composition, classified in classes 530 and 514, subclasses 388.3 and 1, respectively.

VIII. Claims 31-37, drawn to a method crystallizing and co-crystallizing a Hepatitis C virus helicase molecule or molecular complex, classified in class 23, subclass 203. If this Group is elected then the below summarized specie election is also required.

IX. Claims 38-43, drawn to a crystalline Hepatitis C virus helicase and inclusive composition, classified in class 930, subclass 223.

X. Claims 44-46, drawn to a method for solving a crystal structure of a crystal of Hepatitis C virus helicase, classified in class 702, subclass 19.

XI. Claims 47-48, drawn to a method for incorporating a chemical entity in a crystal, classified in class 435, subclass 5.

Specie Election Requirement for Groups I, II-V and VIII:

This application contains claims directed to the following patentably distinct species of the claimed invention:

For Groups I and VIII:

Specie A: Hepatitis C virus helicase alone

Specie B: Hepatitis C virus helicase plus a ligand

For Groups II-V:

Specie A: structure coordinates which are domain 1/domain 2 interface amino acids 205-209, 232-238, 415-420, and 460-467

Specie B: structure coordinates which are domain 1 oligonucleotide binding site amino acids 230-232, 255, 269, and 270-272

Specie C: structure coordinates which are domain 2 oligonucleotide binding site amino acids 391-393, 411-413, 415, 416 and 460

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, all claims in Groups I, II-V, and VIII are generic to the above species. This distinctness or independence of a Hepatitis C virus helicase versus a Hepatitis C virus helicase plus a ligand (Groups I and VIII) as well as domain 1/domain 2 interface versus domain 1 oligonucleotide binding site versus domain 2 oligonucleotide binding site (Groups II-V) is described below.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The inventions are distinct, each from the other because of the following reasons: The inventions of Groupings [I-VI and VIII], [I (Hepatitis C virus helicase specie)], [I (Hepatitis C virus helicase plus ligand specie)], [II (domain 1/domain 2 interface specie)], [II (domain 1 oligonucleotide binding site specie)], [II (domain 2 oligonucleotide binding site specie)], [III (domain 1/domain 2 interface specie)], [III (domain 1 oligonucleotide binding site specie)], [III (domain 2 oligonucleotide binding site specie)], [IV (domain 1/domain 2 interface specie)], [IV (domain 1 oligonucleotide binding site specie)], [IV (domain 2 oligonucleotide binding site specie)], [V (domain 1/domain 2 interface specie)], [V (domain 1 oligonucleotide binding site specie)], [V (domain 2 oligonucleotide binding site specie)], [VIII (Hepatitis C virus helicase specie)], [VIII (Hepatitis C virus helicase plus ligand specie)], [VII], and [IX-XI] are independent inventions because they are directed to different chemical types regarding the critical limitations therein. For Groups I-VI and VIII, the critical feature is a molecule or molecular complex. For Group I (Hepatitis C virus helicase specie), the critical feature

is a Hepatitis C virus helicase. For Group I (Hepatitis C virus helicase plus ligand specie), the critical feature is a Hepatitis C virus helicase plus a ligand. For Groups II-V (domain 1/domain 2 interface specie), the critical features are domain 1/domain 2 interfaces. For Groups II-V (domain 1 oligonucleotide binding site specie), the critical features are domain 1 oligonucleotide binding sites. For Groups II-V (domain 2 oligonucleotide binding site specie), the critical features are domain 2 oligonucleotide binding sites. For Group VIII (Hepatitis C virus helicase specie), the critical feature is a Hepatitis C virus helicase. For Group VIII (Hepatitis C virus helicase plus ligand specie), the critical feature is a Hepatitis C virus helicase plus a ligand. For Group VII, the critical feature is an inhibitor. For Groups IX-XI, the critical feature is a crystalline Hepatitis C virus helicase. The completely separate chemical and entity types of the invention Groups are often separately characterized and published in literature, thus adding to the search burden if all Groups were examined together. Also, processing that may connect two Groups does not prevent them from being considered distinct because enough processing can result in the production of any composition from another composition as long as the processing is not limited in occurrences such as subtractions, additions, and enzymatic action. Thus, the nineteen Groupings [I-VI and VIII], [I (Hepatitis C virus helicase specie)], [I (Hepatitis C virus helicase plus ligand specie)], [II (domain 1/domain 2 interface specie)], [II (domain 1 oligonucleotide binding site specie)], [II (domain 2 oligonucleotide binding site specie)], [III (domain 1/domain 2 interface specie)], [III (domain 1 oligonucleotide binding site specie)], [III (domain 2 oligonucleotide binding site specie)], [IV (domain 1/domain 2 interface specie)], [IV

(domain 1 oligonucleotide binding site specie)], [IV (domain 2 oligonucleotide binding site specie)], [V (domain 1/domain 2 interface specie)], [V (domain 1 oligonucleotide binding site specie)], [V (domain 2 oligonucleotide binding site specie)], [VIII (Hepatitis C virus helicase specie)], [VIII (Hepatitis C virus helicase plus ligand specie)], [VII], and [IX-XI] are independent and/or distinct invention types for restriction purposes.

Inventions in Groups I-VI and VIII are related as product and the process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the molecule or molecular complex of Group I may be utilized in distinct usages as needed in Group II for a scalable three-dimensional configuration of points, in a method for obtaining structural information about a molecule or a molecular complex as in Group III, in a method for homology modeling a Hepatitis C virus helicase homolog as in Group IV, in a computer-assisted method for identifying an inhibitor of Hepatitis C virus helicase activity as in Group V, in a method of making an inhibitor of Hepatitis C virus helicase activity as in Group VI, in a method for crystallizing and co-crystallizing a Hepatitis C virus helicase molecule or molecular complex as in Group VIII, or alternatively, in making antibodies or producing T cells. All of these usages are distinct as requiring distinct and different functions thereof without overlapping search due to different subject matter. This lack of overlapping searches documents the undue search burden if they were searched together.

Inventions in Groups IX-XI are related as product and the process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the crystalline Hepatitis C virus helicase of Group IX may be utilized in distinct usages as needed in Group X for a method of solving a crystal structure of a crystal, in a method for incorporating a chemical entity in a crystal as in Group XI, or alternatively, in detecting a disease. All of these usages are distinct as requiring distinct and different functions thereof without overlapping search due to different subject matter. This lack of overlapping searches documents the undue search burden if they were searched together.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (703) 308-6043. The examiner can normally be reached Monday through Friday from 9 A.M. to 5:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst Tina Plunkett whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

September 9, 2002

ARDIN H. MARSCHEL
PRIMARY EXAMINER